REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated August 18, 2005 (the "Office Action"). Claims 1, 4, 7, 9, 11, 12, 14, 25-27, 29 and 31-47 are pending in the present application upon entry of the present Amendment. Claims 9, 11, 12, 14, 25-27 and 31-46 stand withdrawn from consideration. Claims 1, 4, 7 and 29 are presently under consideration, and Claims 1, 4, 7 and 29 stand rejected. Claims 1, 4, 7 and 29 have been amended, and Applicants have added new Claim 47. Support for these amendments and new claim can be found throughout the specification and claims as originally filed. Applicants believe that no new matter has been added by introduction of these amendments and the new claim. The issues raised in the Office Action are addressed below.

I. Claim Rejections Under 35 U.S.C. §112

The Examiner maintains the rejection of Claims 1, 4, 7 and 29 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action, page 2. For at least reasons already of record, Applicants respectfully disagree.

In an effort to expedite prosecution, however, Applicants have amended Claim 1 to recite as follows:

> An isolated nucleic acid encoding a latency promoter, wherein the latency promoter is operatively linked to a heterologous gene and is capable of driving expression of said heterologous gene and, wherein the latency promoter is encoded by at least 630 bp of nucleotides 4-633 of SEQ ID NO: 1 and up to 2000 bp of nucleotides 4-2,003 of SEQ ID NO: 1 of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of HVS, as set forth in SEQ ID NO:1.

Support for this amendment can be found throughout the specification and claims as originally filed, for example, page 17, line 4-14, where fragments of 630, 1000, 1500 and 2000 bp immediately upstream of ORF 73 were shown to drive heterologous gene expression in human 293T cells.

Further, Claims 4, 7 and 29 have been amended to be consistent with amended Claim 1. Applicants respectfully submit that one skilled in the art would be able to readily envisage a genus of nucleotide sequences having characteristics recited in the claims as amended based upon the written description provided in the specification.

Accordingly, Applicants respectfully submit that Claims 1, 4, 7, 29 and new Claim 47 are supported by the specification as filed, and Applicants request that the rejection under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement be withdrawn.

II. Claim Rejections Under 35 U.S.C. §102

Claims 1, 4, 7 and 29 remain rejected under 35 U.S.C. §102(b) as being anticipated by Nicholas et al. (Virol. **188**: 296-310 (1992) ("Nicholas et al."). *See* Office Action, page 4. More specifically, the Office Action states that "claims that further limit the latency promoter coding portion of the claimed nucleic acid, as opposed to the claimed nucleic acid itself, to a certain specified length does not distinguish the claimed nucleic acid from the nucleic acid comprised in the composition of Nicholas et al." Office Action, page 4.

Applicants have amended Claim 1 to specifically recite portions of SEQ ID NO: 1 as suggested by the Examiner. *See* Office Action, page 3. Support for this amendment can be found throughout the specification and claims as originally filed.

Nicholas et al. describes the 43,658 bp of a contiguous nucleotide sequence comprising the right terminal region of the unique protein coding component (L-DNA) of the HSV genome. Nicholas et al. discusses the identification of conserved sequences between HVS and Epstein-Barr Virus and shows that a general co-linearity exists between the two genomes. However, Nicholas et al. **does not** discuss a latency promoter or its use to drive expression of heterologous gene expression in human cells as is disclosed in the present application and recited in the pending claims. There is no indication in Nicholas et al. of function or of a promoter that can be

used, when operatively linked, to drive heterologous gene expression in human cells. Thus, Applicants respectfully submit that Nicholas et al. does not teach **each and every** recitation of the amended claims as required to establish anticipation under 35 U.S.C. § 102. Moreover, Nicholas et al. fails to provide an enabling disclosure in view of the deficiencies discussed above.

Accordingly, Applicants respectfully submit that Claims 1, 4, 7 and 29 are not anticipated under 35 U.S.C. § 102 by Nicholas et al., and Applicants request that the rejection of these claims be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly, if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,

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CERTIFICATION OF FACSIMILE TRANSMISSION UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office via facsimile number 571-273-8300 on December 19, 2005.

Amelia Tauchen
Date of Signature: December 19, 2005